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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,041	11/07/2005	Gary Levy	9579-90	1924
1059	7590	06/06/2007		
BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA			EXAMINER HADDAD, MAHER M	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 06/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/502,041		LEVY ET AL.	
	Examiner		Art Unit	
	Maher M. Haddad		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Applicant's amendment, filed on 7/29/04, is acknowledged.
2. Claims 1-19 are pending.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 3, 5, 6-8, 12-13, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is an antibody that binds to porcine fgl2, wherein the immune response involved in graft rejection.
- II. Claims 4-5, 6-8, 12, 14, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is an antisense oligonucleotide that is complementary to the porcine fgl2 sequence, wherein the immune response involved in graft rejection.
- III. Claims 6-8, 12, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is a porcine fgl2 protein, wherein the immune response involved in graft rejection.
- IV. Claims 3, 5, 6-7, 9, 12-13, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is an antibody that binds to porcine fgl2, wherein the immune response involved in fetal loss.

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- V. Claims 4-5, 6-7, 9, 12, 14, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is an antisense oligonucleotide that is complementary to the porcine fgl2 sequence, wherein the immune response involved in fetal loss.
- VI. Claims 6-7, 9, 12, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is a porcine fgl2 protein, wherein the immune response involved in a fetal loss.
- VII. Claims 3, 5, 6-7, 10, 12-13, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is an antibody that binds to porcine fgl2, wherein the immune response involved in a viral infection.
- VIII. Claims 4-5, 6-7, 10, 12, 14, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is an antisense oligonucleotide that is complementary to the porcine fgl2 sequence, wherein the immune response involved in a viral infection.
- IX. Claims 6-7, 10, 12, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is a porcine fgl2 protein, wherein the immune response involved in a viral infection.
- X. Claims 3, 5, 6-7, 11, 12-13, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is an antibody that binds to porcine fgl2, wherein the immune response involved in a hepatitis-like disease.
- XI. Claims 4-5, 6-7, 11, 12, 14, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is an antisense oligonucleotide that is

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complementary to the porcine fgl2 sequence, wherein the immune response involved in a hepatitis-like disease.

- XII. Claims 6-7, 11, 12, drawn to a method of inhibiting or suppressing an immune response to a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient, wherein the agent is a porcine fgl2 protein, wherein the immune response involved in a hepatitis-like disease.
- XIII. Claim 2, drawn to a method of inhibiting or preventing thrombosis associated with xenotransplant rejection of a porcine organ or tissue comprising administering an effective amount of an agent that inhibits porcine fgl2 to the porcine organ or tissue, porcine donor or transplant recipient.
- XIV. Claims 15-16 and 19, drawn to an isolated porcine fgl2 nucleic acid molecule having a nucleic acid sequence of SEQ ID NO:1 or a homolog or analog thereof.
- XV. Claim 17, drawn to an isolated porcine fgl2 protein having SEQ ID NO:2.
- XVI. Claim 18 drawn to an antibody that binds to an isolated porcine fgl2 protein having SEQ ID NO:2.

Claim 1 links inventions I-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim 1. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group XVI was found to have no special technical feature that defined the contribution over the prior art of Levy et al (US Pat. No. 6,403,089) (see entire document).

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Levy et al teach an antibody that binds Fgl2, wherein the antibody binds an epitope comprising the amino acids DRYPSGNCGLYY (see patented claims 1-4 in particular). DRYPSGNCGLYY is 100% identical to amino acids 367-378 of claimed SEQ ID NO:2.


Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 24, 2007



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